NOV 1 3 2002

K014030

510(K) Summary

Pursuant to 510 (i) of the Federal Food, Drug, and Cosmetic Act, as Amended.

Company Name: .Centerpulse Dental
Address: 1900 Aston Avenue, Carlsbad, CA 92008-7308
Telephone Number: 760-929-4300
Registration Number : 2023141
Contact Person: Paula Morgan
Date Summary Prepared: November 12, 2002
Classification Name: Abutment
Common/Usual Name: Abutment for Dental Implant System
Device Trade Name: Hex-Lock Temporary Abutment

The Primary device used for comparison in this summary is ProTect abutment from Friadent. The ProTect abutment from Friadent is manufactured by FRIADENT GmbH.

1. Intended Use: **(The statements of intended use are identical)**

The Hex-Lock Temporary Abutment is designated for use on the internal hexagon implant interface for less than twenty-eight days usage which is placed in the edentulous mandibles or maxillae, for fixation of a final crown. The intended use of the Hex-Lock Temporary Abutment is identical to the intended use of the predicate device, the ProTect abutment from Friadent. The plastic temporary abutment is intended to be used to create an esthetic emergence through the gingiva between implant uncovering and final restoration with screw-retained or cemented restorations. **Use of the plastic abutment is not to exceed twenty-eight (28) days**. If time between placement of temporary abutment and final restoration needs to exceed twenty-eight (28) days then the use of a titanium abutment, which is indicated for longer-term use, is required.
. The abutment can be used for either a single tooth or multiple tooth unit provisional restoration and can be modified in height to suit individual needs during the fabrication of the provisional prosthesis.

2. Description:

The Hex-Lock Temporary Abutment is available in 4.5mm, 5.5mm, and 6.5mm outer diameter lengths for the internal hexagon interface. The abutment/implant platform diameter is 3.5mm, 4.5mm, and 5.7mm for the internal hexagon interface. All the abutments exhibit the internal hexagon interface.

3. Technological Characteristics:

The Hex-Lock Temporary Abutment is a new abutment design that is being submitted to interact with an internal hexagon dental implant system. The abutment features an internal hex engaging plastic cylinder with retentive parallel walls and a flared cuff used for short term restorations less than twenty-eight (28) days. This abutment will attach directly to the implant with a retaining screw with a long shaft that protrudes from the top of the abutment to facilitate the fabrication of the provisional prosthesis. Both screws allow for length reduction for custom height restorations. The abutment will exhibit the internal hex engaging feature. The abutment/implant interface remains unchanged.

4. Comparison Analysis:

The overall design of the Hex-Lock Temporary Abutments are identical to the predicate abutment. See Table 1 below for a comparison of the Hex-Lock Temporary Abutment and the predicate implant.

Feature	Hex-Lock Temporary Abutment	Predicate Abutment
Abutment Body Geometry	Straight Retentive Wall	Straight Retentive Wall
Abutment Diameters	4.5mm, 5.5mm, 6.5mm	3.4mm, 3.8mm, 4.5mm, 5.5mm, & 6.5mm
Abutment/Implant Diameter	3.5mm, 4.5mm, 5.7mm	3.4mm, 3.8mm, 4.5mm, 5.5mm, & 6.5mm
Abutment Body Material	Ultem	PEEK
Implant/Abutment Interface	Hex anti-rotational interface	Hex anti-rotantional interface
Manufacturing Site	Carlsbad, CA	Mannheim, Germany
Packaging	Tyvek® tray in chipboard box.	Blister pack combined w/ cardboard outer wrap.
Sterile	Yes	No

Table: 1 Summary of Comparison

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 2002

Ms. Paula Morgan
Manager, Regulatory Affairs
Sulzer Dental, Incorporated
1900 Aston Avenue
Carlsbad, California 92008-7308

Re: K014050
Trade/Device Name: Hex-Lock Temporary Abutment
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: August 23, 2002
Received: August 26, 2002

Dear Ms. Morgan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known): K014050

Device Name: Hex-Lock Temporary Abutment

Indications for Use:

The plastic temporary abutment can be used to create esthetic, screw-retained or cemented provisional restorations at second stage uncovering. Once the restoration has been applied to the temporary abutment, it can be used to develop a more esthetic emergence profile. Temporary abutment is not to be used as a permanent abutment. Not to exceed 28-days of placement.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K014050